

Remarks

Claims 36-56 are pending in the application. Claim 36 has been amended. Applicant believes this amendment serves to clarify the present invention and is independent of patentability.

Allowable Subject Matter

Applicant acknowledges with appreciation that claims 45-56 were indicated as being allowed.

Request for Reconsideration of Final Rejection

Applicant respectfully requests reconsideration of the finality of the rejection. Second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 C.F.R. §1.97(c) with the fee set forth in 37 C.F.R. §1.17(p). *See* MPEP §706.07(a).

Applicant recognizes that independent claim 36 was the only claim in which Applicant amended in the previous response and which the Examiner has currently rejected. Therefore, it is Applicant's understanding that the Examiner believes the amendments made to claim 36 necessitated a new ground of rejection presented in this Office action, which was made final.

The amendments of claim 36 in the previous response were made in response to a 35 U.S.C. §112, first paragraph rejection. In addition to pointing out support in the specification for the claimed subject matter, Applicant changed "first human body" to "donor" and changed "second human body" to "patient". Applicant respectfully contends that the terminology change to "donor" and "patient" should not have necessitated a final Office action.

In this Office action, claim 36 was rejected under 35 U.S.C. §103(a) as being unpatentable over Washington University Law Quarterly, "Fetal Tissue Transplants," by John A. Robertson (hereinafter "Robertson") in view of U.S. Patent No. 3,804,089 to Bridgman (hereinafter "Bridgman 1974"). Claim 36 was also rejected under §103(a) as being unpatentable

over Robertson in view of U.S. Patent No. 3,670,732 to Robinson. Finally, claim 36 was rejected under §103(a) as being unpatentable over Robertson in view of U.S. Patent No. 3,939,835 to Bridgman (hereinafter "Bridgman 1976").

In brief, Bridgman 1974, Robinson, and Bridgman 1976 teach the removal of a fetus from a uterus using a vacuum curette or cannula (see Abstracts). Simply stated, the removal of a fetus (an abortion) is performed on a carrier or mother. In claim 36, the pre-amended term, "first human body", was used to describe from where fetal tissue was removed. The term, "first human body", includes a carrier or mother undergoing an abortion. Therefore, pre-amended claim 36, using "first human body", could have been rejected in the previous Office action based on the currently cited references.

Additionally, Robertson teaches the transplantation of fetal tissue to cure sick patients (p. 444). In claim 36, the pre-amended term, "second human body", was used to describe where fetal tissue was implanted. Generally, a sick patient of Robertson is a human body. Therefore, pre-amended claim 36, using "second human body", could have been rejected in the previous Office action based on the currently cited references.

Finally, Applicant respectfully points out that the ground of rejection in this Office action is based on the Examiner's cited references and not an information disclosure statement filed by Applicant during the period set forth in 37 C.F.R. §1.97(c) with the fee set forth in 37 C.F.R. §1.17(p).

In light of the foregoing, Applicant respectfully requests reconsideration of the finality of the rejection. Applicant respectfully contends that the new ground of rejection was neither necessitated by Applicant's amendment of claim 36 nor based on information submitted by the Applicant in an information disclosure statement.

35 U.S.C. §103 Rejection based on Robertson in view of Bridgman 1974

Claims 36, 37 and 40 were rejected under 35 U.S.C. §103(a) as being unpatentable over Robertson in view of Bridgman 1974. Specifically, the Examiner states that:

Robertson discloses on page 444, paragraph 4, that fetal tissue may be used as an "effective therapy" for "severe chronic diseases"...Although it is not stated in the

claims or the specification whether the donor is the fetus or the mother, The donor is considered the carrier or the mother...Bridgman [1974] teaches a tool (Figs. 1-2) used for performing an abortion under the influence of suction (Abstract). Since the procedure is an abortion, inherently it is performed percutaneously. Col. 2, lines 18-24 disclose that irrigation may occur either "constantly or intermittently." Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to remove the tissue as taught by Robinson in order to abort the fetus. The fetus tissue inherently is broken into portions during extraction.

For the reasons set forth below, Applicant respectfully submits that the rejected claims are not taught or suggested by the references, either alone or in combination.

Robertson discloses that "the one and a half million abortions performed annually in the United States appear adequate to supply fetal tissue for research and therapy for the foreseeable future" (p. 446) and that "only recently has the possibility of transplanting fetal tissue to cure or alleviate symptoms in sick patients seemed feasible on a large scale" (p. 444). Meanwhile, Bridgman 1974 discloses a vacuum curette for use with uterine aspirator apparatus (Abstract). The apparatus is inserted carefully into the vagina and cervix, suction is then started, and debris from the conceptus is removed (col. 1, lines 32-48).

In contrast, Applicant teaches a percutaneous tissue removal apparatus including a flexible drill shaft and means for transmitting motion to the shaft (p. 1, lines 20-22). Because the drill shaft is flexible, the surgeon can guide the cutting tip into various locations within the tissue from a small (percutaneous) incision (p. 3, lines 2-5). One or more selected components of the removed tissue fragments may be collected for implantation, preferably into the body of the patient from whom they were removed (p. 2, line 26 to p. 3, line 2).

Applicant respectfully contends that the cited references do not teach or suggest at least one element of the rejected claims. According to Dorland's Pocket Medical Dictionary (23d ed. 1982), percutaneous is defined as "performed through the skin." Applicant discloses the removal of tissue, including fetal tissue, through a small percutaneous incision. That is, fetal tissue is removed through an incision in the skin. In contrast, Bridgman 1974 teaches the removal of tissue through the cervix and vagina, while Robertson similarly teaches the removal of tissue via an abortion.

To highlight this distinction, Applicant has amended claim 36 to include the step of removing fetal tissue from a donor through a percutaneous incision.

Based on the amendment and remarks above, Applicant respectfully submits that the references do not expressly or impliedly suggest the claimed invention. Accordingly, Applicant submits that the 35 U.S.C. § 103(a) rejection of claims 36 should be withdrawn. Based on at least there dependency, claims 37 and 40 are allowable as well.

35 U.S.C. §103 Rejection based on Robertson in view of Robinson

Claims 36, 38 and 39 were rejected under 35 U.S.C. §103(a) as being unpatentable over Robertson in view of Robinson. Specifically, the Examiner states that:

Robertson meets the limitations of the claims as described but fails to disclose a method of removing the fetus. Nevertheless, Robinson discloses a method of removing the fetus, wherein the tissue is sucked while rotating and reciprocating motion are used to cut the tissue (Abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to remove the tissue as taught by Robinson in order to abort the fetus.

For the reasons set forth below, Applicant respectfully submits that the rejected claims are not taught or suggested by the references, either alone or in combination.

Robertson discloses that “the one and a half million abortions performed annually in the United States appear adequate to supply fetal tissue for research and therapy for the foreseeable future” (p. 446) and that “only recently has the possibility of transplanting fetal tissue to cure or alleviate symptoms in sick patients seemed feasible on a large scale” (p. 444). Meanwhile, Robinson discloses a curette for emptying a gravid uterus of the products of the first trimester of pregnancy (Abstract). The curette includes an open-ended sleeve which is of a suitable diameter to permit insertion thereof through the cervix into the uterine canal and a tube which is reciprocable and rotatably carried within the sleeve (col. 1, lines 61-65).

In contrast, Applicant teaches a percutaneous tissue removal apparatus including a flexible drill shaft and means for transmitting motion to the shaft (p. 1, lines 20-22). Because the drill shaft is flexible, the surgeon can guide the cutting tip into various locations within the tissue

from a small (percutaneous) incision (p. 3, lines 2-5). One or more selected components of the removed tissue fragments may be collected for implantation, preferably into the body of the patient from whom they were removed (p. 2, line 26 to p. 3, line 2).

Applicant respectfully contends that the cited references do not teach or suggest at least one element of the rejected claims. According to Dorland's Pocket Medical Dictionary (23d ed. 1982), percutaneous is defined as "performed through the skin." Applicant discloses the removal of tissue, including fetal tissue, through a small percutaneous incision. That is, fetal tissue is removed through an incision in the skin. In contrast, Bridgman 1974 teaches the removal of tissue through the cervix and vagina, while Robertson similarly teaches the removal of tissue via an abortion.

To highlight this distinction, Applicant has amended claim 36 to include the step of removing fetal tissue from a donor through a percutaneous incision.

Based on the amendment and remarks above, Applicant respectfully submits that the references do not expressly or impliedly suggest the claimed invention. Accordingly, Applicant submits that the 35 U.S.C. § 103(a) rejection of claims 36 should be withdrawn. Based on at least there dependency, claims 38 and 39 are allowable as well.

35 U.S.C. §103 Rejection based on Robertson in view of Bridgman 1976

Claims 36 and 43 were rejected under 35 U.S.C. §103(a) as being unpatentable over Robertson in view of Bridgman 1976. Specifically, the Examiner states that:

Robertson meets the limitations of the claims as described but fails to disclose a method of removing the fetus. Nevertheless, Bridgman [1976] teaches a method of aspirating and removing an aborted fetus, including the passage (the collection bottle) having a filter 14 (col. 4, lines 65 – col. 5 line 3). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to remove the tissue as taught by Bridgman [1976] in order to abort the fetus.

For the reasons set forth below, Applicant respectfully submits that the rejected claims are not taught or suggested by the references, either alone or in combination.

Robertson discloses that "the one and a half million abortions performed annually in the

United States appear adequate to supply fetal tissue for research and therapy for the foreseeable future” (p. 446) and that “only recently has the possibility of transplanting fetal tissue to cure or alleviate symptoms in sick patients seemed feasible on a large scale” (p. 444).

Bridgman 1976 discloses a medical aspiration system vacuum level indicator to be used, preferably, for vacuum abortions and diagnostics (Abstract). The apparatus consists basically of a collection vacuum bottle, a cap valve socket assembly, a mesh filter or trap, and a cannula which fits directly into a socket connection of the cap valve socket assembly (col. 4, lines 7-11). The apparatus is inserted carefully into the vagina and cervix, suction is then started, and debris from the conceptus is removed (col. 1, lines 32-48). More specifically, a sterile cannula is introduced into the uterus, and the surgeon opens the valve of the cap valve socket; and then, by manipulating the bottle with one or both hands, moves the opened end of the cannula over the surface of the uterus wall, extracting the conceptus (col. 5, lines 15-20).

In contrast, Applicant teaches a percutaneous tissue removal apparatus including a flexible drill shaft and means for transmitting motion to the shaft (p. 1, lines 20-22). Because the drill shaft is flexible, the surgeon can guide the cutting tip into various locations within the tissue from a small (percutaneous) incision (p. 3, lines 2-5). One or more selected components of the removed tissue fragments may be collected for implantation, preferably into the body of the patient from whom they were removed (p. 2, line 26 to p. 3, line 2).

Applicant respectfully contends that the cited references do not teach or suggest at least one element of the rejected claims. According to Dorland’s Pocket Medical Dictionary (23d ed. 1982), percutaneous is defined as “performed through the skin.” Applicant discloses the removal of tissue, including fetal tissue, through a small percutaneous incision. That is, fetal tissue is removed through an incision in the skin. In contrast, Bridgman 1974 teaches the removal of tissue through the cervix and vagina, while Robertson similarly teaches the removal of tissue via an abortion.

To highlight this distinction, Applicant has amended claim 36 to include the step of removing fetal tissue from a donor through a percutaneous incision.

Based on the amendment and remarks above, Applicant respectfully submits that the references do not expressly or impliedly suggest the claimed invention. Accordingly, Applicant

submits that the 35 U.S.C. § 103(a) rejection of claims 36 should be withdrawn. Based on at least its dependency, claim 43 is allowable as well.

35 U.S.C. §103 Rejections

Claim 41 was rejected under 35 U.S.C. §103(a) as being unpatentable over Robertson in view of Bridgman 1974, and in further view of U.S. Patent No. 5,190,541 to Abele *et al.*

Claim 42 was rejected under 35 U.S.C. §103(a) as being unpatentable over Robertson in view of Bridgman 1974, and in further view of U.S. Patent No. 4,750,488 to Wuchinich *et al.*

Claim 44 was rejected under 35 U.S.C. §103(a) as being unpatentable over Robertson in view of Bridgman 1976, and in further view of Sabel *et al.*

In response, Applicant respectfully submits that this rejection should be withdrawn. "If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious." *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). Therefore, based on the above amendment and remarks regarding independent claim 36, Applicant submits that dependent claims 41, 42 and 44 are patentable over the cited references.

In any event, Abele does not even qualify as prior art. Abele issued on March 2, 1993 based on an application filed October 17, 1990. The instant application has a priority claim back to June 28, 1990. Accordingly, Applicant respectfully submits that Abele is not prior art to this application.

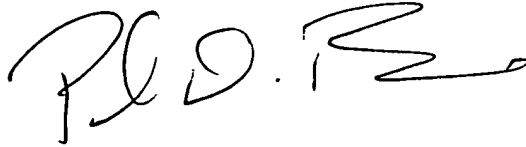
Conclusion

In light of the foregoing, the claim rejections are believed to have been overcome, placing claims 36-44 in condition for allowance, and reconsideration and allowance thereof is respectfully requested.

The Examiner is encouraged to telephone the undersigned to discuss any matter that would expedite allowance of the present application.

No fee is believed to be due. However, please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 780-A02-014-7).

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'P.D. Bianco', with a stylized flourish at the end.

Paul D. Bianco, Reg. # 43,500

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